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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,572	06/18/2001	Reto Naef	4-30754A	2901

1095 7590 12/06/2001

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1619	5

DATE MAILED: 12/06/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/883,572	Applicant(s) NAEF, RETO	
	Examiner Mina Haghighatian	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required. In particular the first paragraph of page 1.

The disclosure is objected to because of the following informalities:

The second paragraph on page 3 is confusing because it reads "the invention includes the use of any compound within the scope of the claims of the patent specifications listed above, particularly the specific compounds disclosed in those specifications, more particularly the specific compounds disclosed in the examples and claims of those specifications". Problem 1: not all the documents listed are patents, such as European Journal of Pharmacology, which does not contain claims. Problem 2: If by referring to the listed documents, the Applicant means to incorporate by reference, it should be noted that the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 14 are vague and indefinite because they contain patent numbers or patent application numbers. Claims can not refer to other documents. Claims 4, 7, 10, 13 and 15-20 are rejected because they are dependent on a rejected claim.

Claims 5-7 are vague and indefinite because the terms "the inhalable form" and "said medicament" lack antecedent basis. Claims 8-14 are rejected due to depending on rejected claims. Claims 11-13 are vague and indefinite due to containing confusing and redundant terminology, by repeating "finely divided particulate form" more than once within each claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless – (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4 and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Sui et al (6,077,841).

Sui teaches substituted 5-heterocyclyl pyrazolopyrimidinones and derivatives thereof, their synthesis and their use in treating sexual dysfunction in mammals, especially male erectile dysfunction. The phosphodiesterase V (PDEV) inhibitor, Sildenafil, 5-[2-ethoxy-5-(4-methylpiperazin-1-ylsulphonyl)phenyl]-1-methyl-3-n-prpyl-6,7-dihydro-1H-pyazolo[4,3-d]pyrimidine-7-one, and a number of related analogues and their use are described in previous publications. To date, at least nine families of mammalian PDEs have been described, five of which are capable of hydrolyzing the active, cGMP, to the inactive, GMP, under physiological conditions (PDE's I,II,V,VI and IX). PDE V is the predominant isoform in human corpus cavernosum. Inhibitors of PDEV, therefore, would be expected to increase the concentration of cGMP in the corpus cavernosum and enhance the duration and frequency of penile erection (col. 1, lines 14-18, 60-66; col. 2, lines 37-51).

Sui also teaches the methods of treating sexual dysfunction, especially male erectile dysfunction, and/or impotence in a subject in need thereof comprising administering to the subject a therapeutically effective amount of any of the compounds or pharmaceutical compositions described. Also a process for making a pharmaceutical composition comprising any of the compounds and a pharmaceutically acceptable carrier (col. 5, lines 49-63).

Sui discloses that some of the compounds may form solvates with water (i.e, hydrates) or common organic solvents (col. 7, lines 55-59).

Sui discloses pharmaceutical compositions comprising one or more compounds of this invention in association with a pharmaceutically acceptable carrier. The preferred

dosage forms are such as tablets, pills, capsules, powders, granules, parenteral solutions and suspensions, metered aerosol or liquid sprays, drops, ampules, autoinjector devices or administration by inhalation or insuffation (col. 9, lines 55-65).

Sui discloses the other derivatives and forms of the inhibitor of cGMP PDE and the method of making compositions in columns 14-30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sui et al '841 in view of Purewal et al (5,225,183).

Sui was discussed above. Sui lacks specific teachings on the use of propellants and the particle size of the powders.

Purewal teaches medicinal aerosol formulations. The suitable propellants are such as 1,1,1,2-tetrafluoroethane, n-butane, isobutane, pentane and isopentanes (col. 1, lines 58-66; col. 2, lines 14-30).

Purewal also teaches that the particle size of the finely divided solid powder should be less than 25 microns in diameter and preferably less than 10 microns in diameter (col. 6, lines 35-53).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general composition of Sui for treating sexual dysfunction through administration by inhalation of an inhibitor of cGMP PDE to a subject in need of such treatment, to have looked in the art for more specific parameters such as particle size and propellant because of the expectations of successfully preparing an effective aerosol or spray form of the said inhibitor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
Patent Eaxminer
November 29, 2001

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
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